Analysis of Proposed Medicare Part B to Part D Shift With Associated Changes in Total Spending and Patient Cost-Sharing for Prescription Drugs

Hwang, Thomas J ; Jain, Nina ; Lauffenburger, Julie C ; Vokinger, Kerstin Noëlle ; Kesselheim, Aaron S

Abstract: Importance: The US Department of Health and Human Services (HHS) has proposed to reform drug pricing in Medicare Part B, which primarily covers physician-administered drugs and biologic agents. One HHS proposal would shift coverage of certain drugs from Medicare Part B to Part D, which is administered by private prescription drug plans. Objective: To estimate the association of changes of a shift in Medicare Part B to Part D with total drug spending and patient cost-sharing. Design, Setting, and Participants: Retrospective drug cohort study of the 75 brand-name drugs associated with the highest Part B expenditures among fee-for-service Medicare beneficiaries in 2016. Main Outcomes and Measures: Estimated total Medicare spending in Part B and Part D; annual out-of-pocket costs in Part B and under the standard 2018 Part D benefit; and proportion of drugs in Part D's protected drug classes (immunosuppressants for prophylaxis of organ transplant rejection, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics). Results: At 2018 prices, total Medicare Part B spending for the 75 brand-name drugs with the highest Part B expenditures was estimated to be $21.6 billion annually. Under the proposed policy, total Part D drug spending for these drugs was estimated to range between 17.6 billion and 20.1 billion after rebates, corresponding to a 6.9% to 18.3% decrease in drug spending in Part D compared with Part B billion (43.9%) in Part B spending, were in protected Part D classes where plans must cover essentially all drugs. For 67 drugs with available information, the prices for 65 (97.0%) were a median of 45.8% to 59.7% lower in comparator high-income countries than Part B drug prices. Median patient cost-sharing in Part B for all 75 brand-name drugs was 4683 (interquartile range [IQR], 1069-9282) per year. Shifting Part B drugs to the 2018 standa of − pocket costs by a median of 860 (IQR, -3884 to 496) among Medicare beneficiaries without Medicaid or Part B supplemental insurance (Medigap). For beneficiaries who would qualify for the low-income subsidy program in Part D, cost-sharing would be lower in Part D than in Part B for all drugs. For beneficiaries with Medigap insurance, estimated Part D out-of-pocket costs exceeded average Medigap premium costs by a median of 1460 for those with Part D coverage and by a median of 1952 for those without Part D coverage. Conclusions and Relevance: Although the HHS proposal to shift certain drugs from Medicare Part B to Part D may reduce total drug spending, it may increase out-of-pocket costs for some Medicare beneficiaries, including those with Medicare supplement insurance. The Department of Health and Human Services should ensure that the proposed reforms benefit both patients and payers.

DOI: https://doi.org/10.1001/jamainternmed.2018.6417

Hwang, Thomas J; Jain, Nina; Lauffenburger, Julie C; Vokinger, Kerstin Noëlle; Kesselheim, Aaron S (2019). Analysis of Proposed Medicare Part B to Part D Shift With Associated Changes in Total Spending and Patient Cost-Sharing for Prescription Drugs. JAMA Internal Medicine, 179(3):374.
DOI: https://doi.org/10.1001/jamainternmed.2018.6417

JAMA Internal Medicine | Original Investigation | HEALTH CARE REFORM

Analysis of Proposed Medicare Part B to Part D Shift With Associated Changes in Total Spending and Patient Cost-Sharing for Prescription Drugs

Thomas J. Hwang, AB; Nina Jain, MD, MBA; Julie C. Lauffenburger, PharmD, PhD; Kerstin N. Vokinger, MD, JD, PhD; Aaron S. Kesselheim, MD, JD, MPH

IMPORTANCE The US Department of Health and Human Services (HHS) has proposed to reform drug pricing in Medicare Part B, which primarily covers physician-administered drugs and biologic agents. One HHS proposal would shift coverage of certain drugs from Medicare Part B to Part D, which is administered by private prescription drug plans.

OBJECTIVE To estimate the association of changes of a shift in Medicare Part B to Part D with total drug spending and patient cost-sharing.

DESIGN, SETTING, AND PARTICIPANTS Retrospective drug cohort study of the 75 brand-name drugs associated with the highest Part B expenditures among fee-for-service Medicare beneficiaries in 2016.

MAIN OUTCOMES AND MEASURES Estimated total Medicare spending in Part B and Part D; annual out-of-pocket costs in Part B and under the standard 2018 Part D benefit; and proportion of drugs in Part D's protected drug classes (immunosuppressants for prophylaxis of organ transplant rejection, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics).

RESULTS At 2018 prices, total Medicare Part B spending for the 75 brand-name drugs with the highest Part B expenditures was estimated to be $21.6 billion annually. Under the proposed policy, total Part D drug spending for these drugs was estimated to range between $17.6 billion and $20.1 billion after rebates, corresponding to a 6.9% to 18.3% decrease in drug spending in Part D compared with Part B. Of the 75 drugs studied, 33 (44.0%) drugs, accounting for $9.5 billion (43.9%) in Part B spending, were in protected Part D classes where plans must cover essentially all drugs. For 67 drugs with available information, the prices for 65 (97.0%) were a median of 45.8% to 59.7% lower in comparator high-income countries than Part B drug prices. Median patient cost-sharing in Part B for all 75 brand-name drugs was $4683 (interquartile range [IQR], $1069-$9282) per year. Shifting Part B drugs to the 2018 standard Part D benefit was projected to decrease out-of-pocket costs by a median of $860 (IQR, −$3884 to $496) among Medicare beneficiaries without Medicaid or Part B supplemental insurance (Medigap). For beneficiaries who would qualify for the low-income subsidy program in Part D, cost-sharing would be lower in Part D than in Part B for all drugs. For beneficiaries with Medigap insurance, estimated Part D out-of-pocket costs exceeded average Medigap premium costs by a median of $1460 for those with Part D coverage and by a median of $1952 for those without Part D coverage.

CONCLUSIONS AND RELEVANCE Although the HHS proposal to shift certain drugs from Medicare Part B to Part D may reduce total drug spending, it may increase out-of-pocket costs for some Medicare beneficiaries, including those with Medicare supplement insurance. The Department of Health and Human Services should ensure that the proposed reforms benefit both patients and payers.

Invited Commentary page 380

Author Audio Interview

Related article page 431

Supplemental content

Author Affiliations: Program on Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts (Hwang, Jain, Lauffenburger, Vokinger, Kesselheim); Faculty of Medicine, University of Zürich and University Hospital Zürich, Zürich, Switzerland (Vokinger).

Corresponding Author: Aaron S. Kesselheim, MD, JD, MPH, Program on Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, 1620 Tremont St, Ste 3030, Boston, MA 02120 (akesselheim@bwh.harvard.edu).

JAMA Intern Med. 2019;179(3):374-380. doi:10.1001/jamainternmed.2018.6417
Published online January 14, 2019.

In 2016, Medicare Part B spending for prescription drugs was $29.1 billion, primarily for medications administered by injection or infusion in physician offices and hospital outpatient departments.[1] Between 2010 and 2016, Medicare Part B drug spending increased by approximately 9.8% on average per year, compared with an average annual growth rate of 8.2% in Medicare Part D program expenditures.[1,2]

In May 2018, the US Department of Health and Human Services (HHS) proposed to shift coverage of certain drugs from Part B to Medicare Part D.[3,4] Both programs cover outpatient prescription drugs but pay for them differently. In Part B, Medicare payments are based on the average sales price, which is the price paid (net of discounts and rebates) by most private purchasers, plus a statutory add-on amount. In Part D, private insurers administer prescription drug plans for Medicare beneficiaries; individual Part D plans (and their pharmacy benefit managers) negotiate with manufacturers to determine the amounts they pay for drugs.

The HHS policy blueprint[5] was published on May 11, 2018. The proposed Medicare Part B reform is an important part of the Trump administration's strategy to lower drug prices and reduce out-of-pocket costs for Medicare beneficiaries.[4] We modeled the effects of the proposed reform on total drug spending and patients' out-of-pocket costs for prescription drugs.

Key Points

Question What are the projected effects of the Department of Health and Human Services (HHS) proposed Medicare Part B drug pricing reform on drug spending and out-of-pocket costs?

Findings In this analysis of 75 brand-name drugs with the highest Part B expenditures in 2016, shifting Medicare Part B drugs to Part D was estimated to decrease total drug spending by 7% to 18% after rebates. Under the standard 2018 Part D benefit, out-of-pocket costs for most drugs were projected to be lower in Part D among fee-for-service Medicare beneficiaries without Medicaid or supplemental insurance in Part B and among those who would qualify for the low-income subsidy program; however, out-of-pocket costs were estimated to increase among beneficiaries with Medicare supplement insurance and among those currently without Part D coverage.

Meaning Although the HHS proposal may reduce total drug spending, it could increase out-of-pocket costs for some Medicare beneficiaries.

Methods

We obtained Part B drug utilization, patient cost-sharing, and total spending data from the Centers for Medicare & Medicaid Services (CMS) Drug Data files, which cover fee-for-service claims.[6] These data files summarize Part B drug claims from physicians, outpatient hospitals, and suppliers, and exclude claims billed using NOC codes ("Not Otherwise Classified") (eg, J3490, J3590, or J9999), claims for which Medicare was not the primary payer, and claims with total spending amounts of $0 associated with the drug (see eMethods in the Supplement).[6] The study drug cohort comprised brand-name drugs associated with the highest Part B expenditures, defined as brand-name drugs with at least $10 million in Part B spending in 2016 (most recent year of data available). Generic drugs, devices, vaccines, blood products and clotting factors, and certain biological products were excluded (eMethods in the Supplement).

The Medicare Prescription Drug Benefit Manual states that Part D plan sponsors must include "all or substantially all" drugs in the 6 protected classes in their formularies.[7] The protected classes are immunosuppressants for prophylaxis of organ transplant rejection, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. We examined how many Part B drugs would fall under Part D's protected classes and may therefore experience limited price competition even if moved into Part D.[8] Two investigators (N.J. and J.C.L.) independently reviewed all approved indications in drug labels and then assigned protected class status (interrater agreement, 97.3%).[9] Per the Medicare Benefit Manual,[7] the investigators considered both new drugs (ie, indications at the time of first US Food and Drug Administration [FDA] approval) as well as newly approved indications since first approval. Drugs were categorized as (1) fully protected class—all approved indications were in a protected class (eg, bortezomib indicated for multiple myeloma and mantle cell lymphoma); (2) partially protected class—at least 1 indication was in a protected class (eg, rituximab indicated for various cancers), but there were some indications that were not in a protected class (eg, rituximab indicated for rheumatoid arthritis); and (3) not protected class—all approved indications were not in a protected class (eg, omalizumab indicated for asthma and chronic idiopathic urticaria). After independent review, the final classifications were made by consensus.

Current annual drug costs were priced for Part B using Medicare's quarterly ASP (Average Sales Price) Drug Pricing file[10] and for Part D using wholesale acquisition costs, which were a median 5.0% to 6.8% lower than reported standard pharmacy costs as of July 2018 (eMethods in the Supplement).[11] Total drug spending in Part B and Part D was estimated using current prices for each program and unadjusted utilization (number of units and beneficiaries) per drug from the latest Medicare Drug Data files. Since Part B drug costs and spending estimates already include rebates, we estimated "net," or rebate-adjusted, drug spending in Part D after accounting for manufacturer rebates and the coverage gap discount (manufacturers provide a 50% discount on drug costs in the coverage gap phase of Part D) (**Table 1**).[12] We obtained Part D rebate levels from HHS,[8] the 2018 Medicare Trustees Report,[2] and an insurance industry–sponsored analysis of rebates for 5 Part D plans.[13] Based on these, Part D spending was adjusted for rebates using an average rebate range of 20.0% to 30.0% for spending on drugs that were not in a protected class and an average rebate range of 0% to 10.0% for spending on drugs in any of the protected classes. Medicare's estimated reinsurance subsidy obligation (that is, reinsurance payments by Medicare to Part D plans) was also adjusted for rebates, using the agency's allocation methodology[14] and a shared rebate fraction of 30.0% to 40.0%.[15] To validate these estimates, in a sensitivity analysis, we also assessed total rebate-adjusted spend-

Table 1. Standard 2018 Medicare Part D Prescription Drug Benefit

Standard Benefit Phase	Standard Benefit Parameters in 2018	Cost-Sharing, %			
		Beneficiaries	Part D Plans	Manufacturers	Medicare
Deductible	Beneficiaries pay 100% of the drug costs until the $405 deductible threshold	100	0	0	0
Initial coverage	Beneficiaries pay 25% coinsurance until an initial coverage limit of $3750	25	75	0	0
Coverage gap	Beneficiaries pay 35% coinsurance for brand-name drugs in the coverage gap until the catastrophic coverage threshold of $8417.60 in estimated total covered Part D spending (or out-of-pocket threshold of $5000)	35	15	50	0
Catastrophic coverage	Beneficiaries pay 5% coinsurance for the rest of the year or $8.35 (for brand-name drugs), whichever is greater	5	15	0	80

Table 2. Categorization of the 33 Brand-Name Study Drugs With Protected Class Status and the Highest Part B Expenditures in 2016

Protected Class[a]	Drugs, No. (%) (n = 33)	
	All Indications	At Least 1 Indication[b]
Antineoplastic	24 (32.0)	6 (8.0)
Immunosuppressant (prophylaxis of organ transplant rejection)	2 (2.7)	0
Antipsychotic	1 (1.3)	0
Anticonvulsant	0	0
Antidepressant	0	0
Antiretroviral	0	0

[a] For assignment of protected class, see the Methods section.

[b] Refers to drugs with at least 1 indication approved by the US Food and Drug Administration and determined to be in a protected Part D class but that also had other nonprotected indications.

ing using drug-specific rebate levels estimated by SSR Health LLC, an investment research firm; SSR's rebate estimates were available for 45 (60%) of the 75 studied drugs (eMethods in the Supplement).[16]

For each drug in the study cohort, we projected annual out-of-pocket costs under current drug prices and the standard 2018 Part D benefit (Table 1) as the base case. Ranges in projected Part D out-of-pocket costs were constructed by varying the coinsurance from 25.0% (standard) to the maximum 33.0% allowable for specialty drugs (defined by Medicare as monthly costs exceeding $670),[17] and by varying annual out-of-pocket costs in Part D on drugs other than the Part B agent from $0 to $1169 (beneficiaries in the top 5% of spending).[18] Current Part B cost-sharing was estimated using current prices and actual cost-sharing amounts (as a percentage of spending) and annual utilization extracted from the Medicare Drug Data files. In the primary analysis, differences in out-of-pocket costs under Part B and Part D were estimated for Medicare beneficiaries without Medicaid or supplemental insurance in Part B.

We descriptively considered possible changes in out-of-pocket costs for beneficiaries without Medicaid who would qualify for the low-income subsidy program.[19,20] The low-income subsidy program lowers out-of-pocket drug costs in Part D for eligible individuals with limited income and resources. We also projected out-of-pocket costs in Part D for beneficiaries with Medicare supplement insurance (Medigap) and for beneficiaries currently without Part D coverage and who would need to purchase it. Medigap can be purchased to cover coinsurance for Part B (but not Part D) drugs. We obtained national average Medigap premiums from the 2016 Medicare Supplement Insurance Experience Reports.[21]

Since the HHS proposal suggested that drugs with lower prices in other countries could be prioritized for the shift from Part B to Part D,[3,5] we compared drug prices between the United States and other countries and considered changes in out-of-pocket costs for these products. In secondary analyses, we examined subsets of drugs in the study cohort to align with policy scenarios proposed by HHS: (1) drugs with prices exceeding the median of those in comparator high-income countries (Germany, Japan, Switzerland, and the United Kingdom); (2) drugs covered by both Part B and Part D; and (3) specialty drugs. Descriptive statistics were calculated using Stata version 12.0 (StataCorp Inc).

Results

The study drug cohort comprised 75 brand-name drugs with the highest Part B expenditures in 2016, with median annual spending per drug of $98.4 million (interquartile range [IQR], $37.9-$268.2 million) (eTable 1 and eFigure 1 in the Supplement). The 75 drugs accounted for $19.8 billion or 77.0% of the $25.7 billion in 2016 fee-for-service Part B drug spending reported in the Medicare Drug Data file. The 3 Part B drugs with the highest associated expenditures were aflibercept (Eylea; Regeneron Pharmaceuticals Inc) with $2.2 billion in spending in 2016, rituximab (Rituxan; Genentech Inc) with $1.7 billion, and pegfilgrastim (Neulasta; Amgen Inc) with $1.4 billion. Thirty-three (44.0%) of the 75 drugs were determined to be in protected Part D classes, of which 30 were antineoplastic agents, 2 were immunosuppressants for prophylaxis of organ transplant rejection, and 1 was an antipsychotic (**Table 2**).

In an advance notice of proposed rulemaking published on October 25, 2018, CMS suggested that Part B drug prices were among the highest in the world and considered directly reducing expenditures for Part B drugs to more closely reflect other countries. Therefore, to assess the magnitude of these price differences, we compared drug prices in Part B and comparator high-income countries. For 67 drugs with available information, 65 (97.0%) had higher prices in Part B than the median of prices in comparator high-income countries. As of May 2018, drug prices in other high-income countries were a median of 45.8% to 59.7% lower than those in Part B (**Figure**).

Estimated Part B and Part D Drug Spending With the Proposed Reforms

With 2018 prices, total estimated Part B spending for all 75 brand-name drugs was $21.6 billion. Under the proposed policy, total Part D spending was estimated to range from $17.6 billion to $20.1 billion after rebates and discounts, corresponding to a 6.9% to 18.3% decrease in total rebate-adjusted spending in Part D compared with Part B (**Table 3**). Total rebate-adjusted drug spending was estimated to decrease by 10.6% to 21.8% if HHS shifted only specialty drugs (defined by Medicare as those with monthly costs exceeding $670) from Part B to Part D. Repeating the primary analysis with drug-specific rebate estimates yielded similar results (eTable 2 in the Supplement). Medicare's estimated reinsurance subsidy obligation was $9.7 billion before rebates and $8.0 billion to $9.0 billion after rebates, accounting for 43.6% to 47.8% of total Part D spending after rebates.

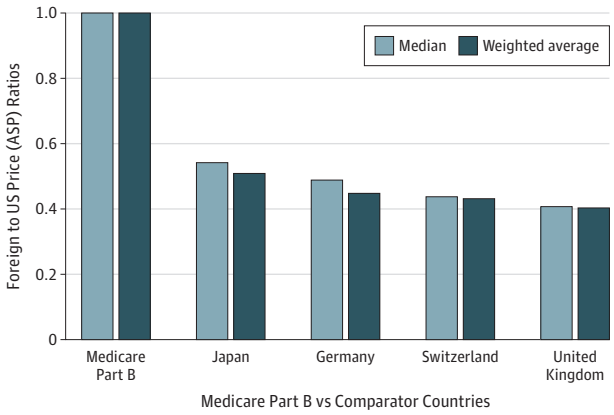
Patient Cost-Sharing

Median estimated patient cost-sharing in Part B for all 75 brand-name drugs was $4683 (IQR, $1069-$9282) at 2018 prices. Shifting Part B drugs to the standard 2018 Part D benefit was projected to decrease out-of-pocket costs by a median of $860 (IQR, −$3884 to $496). When varying coinsurance and spending assumptions, out-of-pocket costs were estimated to increase by at least 10% for 22 to 29 drugs (29.3%-38.9%), and decrease by at least 10% for 41 to 50 drugs (54.7%-66.7%) (**Table 4**). The threshold annual drug cost, for which cost-sharing in the standard Part D benefit would be lower than the coinsurance in Part B, was $15 869 (eFigure 2 in the Supplement). In secondary analyses, results were similar for the scenarios when drugs with prices exceeding the median of prices in comparator high-income countries or drugs covered by both Part B and Part D were shifted to Part D (Table 4). Out-of-pocket costs were estimated to increase for fewer drugs (2-9 drugs, 3.6%-16.4% vs 22-29 drugs, 29.3%-38.9%) if HHS shifted only specialty drugs to Part D.

We also descriptively assessed cost-sharing for the study drugs for 3 additional categories of Medicare beneficiaries. First, for those qualifying for the low-income subsidy program (approximately 5%-10% of fee-for-service Medicare beneficiaries), cost-sharing for brand-name drugs would be $0 to $8.35, depending on income and resources (eMethods in the Supplement). Second, the national average annual premium cost for Medigap insurance was $2216 in 2016. For beneficiaries with Medigap insurance, estimated Part D out-of-pocket costs under the proposed policy exceeded average Medigap premium costs by a median of $1460 (IQR, $171-$2765). The out-of-pocket costs in Part D were estimated to be greater than average Medigap premium costs for 47 to 56 drugs (62.7%-74.7%) and to be lower than Medigap premium costs for 19 to 28 drugs (25.3%-37.3%).

Finally, 12% of Medicare beneficiaries (or approximately 17% of fee-for-service beneficiaries) in 2016 had no Part D coverage or drug coverage that was less generous than Part D's standard benefit.[1] The effects of the proposed policy on out-of-pocket costs would similarly depend on supplemental insurance. After accounting for the average annual premium cost for Part D prescription drug plans ($492 in 2018),[1] the median estimated decrease in out-of-pocket costs under the proposed policy was $368 for the subset of beneficiaries that would need to purchase Part D coverage and do not have Part B supplemental insurance or Medicaid. By contrast, for the subset of beneficiaries with Medigap but not Part D coverage, estimated Part D out-of-pocket costs exceeded average Medigap premium costs by a median of $1952.

Figure. Comparison of Reported Average Sales Prices for Medicare Part B Drugs With Ex-Factory Drug Prices for Other High-Income Countries



The ex-factory price for the selected comparator countries is the price exclusive of sales tax and value-added taxes and adjusted for statutory rebates (but excludes confidential managed access and performance-based rebates in the United Kingdom). Illustrated weighted average ratios are weighted at the drug level by 2016 Medicare Part B expenditures. ASP indicates average sales price; the US ASP = 1. Prices were converted to US dollars at spot exchange rates as of May 18, 2018 (Swiss franc: 1.002; Euro: 1.179; Pound: 1.347; Yen: 0.009).

Discussion

The HHS proposed reforms seek to expand the role of private-sector negotiation of Medicare drug prices by shifting coverage of certain drugs from Part B to Part D. Consistent with the administration's advance notice of proposed rulemaking, we found that drug prices in other high-income countries were substantially lower than Part B drug prices.[22] We estimated that the proposed policy shift from Part B to Part D could reduce total drug spending by 6.9% to 18.3% after accounting for rebates and discounts. However, the potential for greater overall savings was constrained by the fact that 33 (44.0%) of the studied brand-name drugs were in protected classes, which HHS has reported precludes meaningful price negotiation by Part D plans.[8] Furthermore, reinsurance payments by Medicare accounted for roughly half of total estimated Part D spending. It is possible that shifting costly brand-name drugs from Part B to Part D could contribute to the rapid growth in Medicare's reinsurance of Part D drug costs. Between 2010 and 2016, Medicare's reinsurance spending increased by an average of 21.2% per year, and reinsurance payments became the single largest component of Part D spending in 2014.[1,2] Since Medicare pays 80% of drug costs in the catastrophic coverage phase,

Table 3. 2018 Total Estimated Drug Spending in Medicare Parts B and D[a]

Scope of Part B to Part D Shifting Proposal	Drugs, No. (%)	Total Estimated Drug Spending, $US Billions			Decrease in Net Spending From Part B to Part D, Range, %[b]
		Part B Current Policy	Part D Proposed Policy		
			Before Est Rebates[b]	After Est Rebates[b]	
All top-spend Part B drugs in study cohort	75 (100.0)	21.6	24.6	17.6-20.1	6.9-18.3
Secondary analyses					
Top-spend Part B drugs with prices exceeding median of other high-income countries[c]	65 (97.0)	20.5	23.3	16.7-19.1	7.2-18.5
Top-spend Part B drugs also covered by Part D	58 (77.3)	16.8	19.8	14.7-16.7	0.7-12.5
Top-spend Part B specialty drugs[d]	55 (73.3)	17.3	19.3	13.5-15.5	10.6-21.8

Abbreviation: Est, estimated; IQR, interquartile range.

[a] Represents total estimated drug spending. 2018 drug costs were estimated using average sales prices (ASP) for Part B and wholesale acquisition costs (WAC) as of May 18, 2018 for Part D.

[b] See the Methods section for rebate estimates; comparison of estimated net (rebate-adjusted) drug spending refers to Part B drug spending vs estimated Part D drug spending after accounting for rebates and coverage gap discount.

[c] Calculated as a proportion of Part B drugs for which foreign prices were available (n = 67); comparator high-income countries were Germany, Japan, Switzerland, and United Kingdom; 2 enzyme-replacement therapies (velaglucerase alfa and imiglucerase) were less expensive in the United States.

[d] Specialty drugs are defined by Medicare as those with monthly costs exceeding $670.

Table 4. Medicare Patient Cost-Sharing in Part B and Under Different Proposed Part D Shift Scenarios[a]

Scope of Part B to Part D Shifting Proposal	Drugs, No. (%)	Median (IQR)		Drugs With Estimated Change in OOP Costs, No. (%)[b]		
		Part B Current Policy, Estimated Beneficiary OOP Cost	Part D Proposed Policy Projected Beneficiary OOP Cost[b]	Increase ≥10%	Decrease ≥10%	Change <10%
All top-spend Part B drugs in study cohort	75 (100.0)	4683 (1069-9282)	2680-3943 (1736-5249)	22-29 (29.3-38.9)	41-50 (54.7-66.7)	3-6 (4.0-8.0)
Secondary analyses						
Top-spend Part B drugs with prices exceeding median of other high-income countries[c]	65 (97.0)	4683 (1230-8247)	2656-3919 (1807-4900)	18-25 (27.7-38.4)	35-44 (53.8-67.7)	3-6 (4.6-9.2)
Top-spend Part B drugs also covered by Part D	58 (77.3)	4673 (1223-8329)	2668-3931 (1813-4869)	16-21 (27.6-36.2)	32-40 (55.2-69.0)	2-6 (3.4-10.3)
Top-spend Part B specialty drugs[d]	55 (73.3)	5783 (4037-11 655)	3054-4317 (2537-7244)	2-9 (3.6-16.4)	41-50 (74.5-90.9)	3-6 (5.5-10.9)

Abbreviations: IQR, interquartile range; OOP, out-of-pocket.

[a] Estimated for fee-for-service Medicare beneficiaries without Medicaid or supplemental insurance in Part B.

[b] Based on standard Part D drug benefit for 2018. Ranges were constructed by varying coinsurance from 25.0% to 33.0% (specialty drugs only) and annual out-of-pocket costs in Part D, on drugs other than the Part B agent, from $0 to $1169 (average out-of-pocket spending on drugs for beneficiaries in the top 5% of spending).

[c] Calculated as a proportion of Part B drugs for which foreign prices were available (n = 67); comparator high-income countries were Germany, Japan, Switzerland, and United Kingdom; 2 enzyme-replacement therapies (velaglucerase alfa and imiglucerase) were less expensive in the United States.

[d] Specialty drugs are defined by Medicare as those with monthly costs exceeding $670.

in the medium to long-term, the expanding reinsurance component of the Part D benefit may attenuate—or potentially even eliminate—the incentive for Part D plans to obtain the lowest drug costs for beneficiaries and the government.[23-25]

Our analysis also indicates that the proposed policy reform could have a material impact on patients' out-of-pocket costs, with effects varying by drug and patients' insurance in addition to Medicare. We estimated that moving drug coverage from Part B to Part D could decrease out-of-pocket costs among patients without supplemental insurance for the majority of drugs, while increasing cost-sharing for 29.3% to 38.9% of products (22-29 drugs) (or 3.6%-16.4% if limited to high-cost specialty drugs; 2-9 drugs). The favorable impact of this policy shift on cost-sharing would be greatest for beneficiaries who qualify for the Part D low-income subsidy, which can eliminate the coinsurance liability based on income and resources. By contrast, for patients with Medigap insurance, out-of-pocket costs in Part D were estimated to exceed the annual premium costs for supplemental insurance for 62.7% to 74.7% of drugs (47-56 drugs). Out-of-pocket costs would be increased under the proposed policy for beneficiaries with Medigap but without Part D coverage.

Limitations

Our study has limitations. First, the study did not account for possible effects of this proposed reform on insurance premiums or drug utilization. Further actuarial analysis is needed to more precisely determine the financial impact by stakeholder (eg, incurred costs for Medicare vs Part D plans). Second, the study did not include beneficiaries dually eligible for Medicare and Medicaid (who would likely have no or minimal change in cost-sharing due to eligibility for the low-income subsidy in Part D) or those enrolled in employer-sponsored retiree health plans. The HHS proposal would also

likely only apply to fee-for-service Medicare, which covers roughly 67% of Medicare beneficiaries.[1] In August 2018, CMS issued guidance for the Medicare Advantage program that would parallel the proposed Part B to Part D shift for fee-for-service Medicare.[26,27] Specifically, the guidance permits Medicare Advantage plans to apply step therapy to control the utilization of Part B drugs and to cross-manage their Part B and Part D drug benefits (eg, by requiring Part D drug therapy prior to covering a Part B drug) for new prescriptions beginning in January 2019.[26] The CMS anticipates that its guidance could yield savings of 15% to 20% for physician-administered drugs,[27] which is consistent with our estimate for fee-for-service Medicare. Finally, while rebate amounts are confidential, we used current disclosures from HHS and insurers, as well as an industry database of drug-specific rebate amounts, as the best available estimates of Part D rebate levels, and our estimates are in line with those from prior studies.[28] Final incurred net costs in Part D may differ from the estimates presented here.

Conclusions

The limitations of the present study are unlikely to substantially change the overall conclusion that significant savings through rebates offered by manufacturers to Part D plans and their pharmacy benefit managers would be needed to justify the potential financial impact of this policy shift for the Medicare program and for beneficiaries. Recent analyses by the Congressional Budget Office[29] and the White House's Office of Management and Budget[30] did not quantify the savings to the federal government from this policy. To achieve long-term cost-savings, additional reforms may need to be implemented simultaneously, through HHS rulemaking or legislation. Such reforms might include value-based pricing,[31] flexible formularies that improve the ability of plans to negotiate lower prices for drugs in protected classes, and reducing the government's reinsurance subsidy in Part D, as has been proposed by the Medicare Payment Advisory Commission.[32] Policy implementation (eg, through a demonstration project) should be accompanied by rigorous monitoring of patient health outcomes, access, and quality of care. In the interim, while the potentially offsetting effect of reforms on premiums would need to be assessed, HHS could consider capping out-of-pocket costs, or sharing some of the savings from increased rebates with beneficiaries. As it implements this proposal, HHS should ensure that the proposed reforms benefit both patients and payers.

ARTICLE INFORMATION

Accepted for Publication: September 24, 2018.

Published Online: January 14, 2019. doi:10.1001/jamainternmed.2018.6417

Author Contributions: Mr Hwang had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Hwang, Jain, Kesselheim.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Hwang, Jain.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Hwang.
Obtained funding: Kesselheim.
Administrative, technical, or material support: Vokinger.
Supervision: Kesselheim.

Conflict of Interest Disclosures: Mr Hwang reports prior employment by Blackstone and Bain Capital, which have invested in health care companies. Dr Jain reports an award in a business case competition sponsored by Merck. Dr Lauffenburger reports unrestricted research funding payable to her institution from AstraZeneca and Sanofi. Dr Kesselheim reports an honorarium for a talk at CVS Caremark in 2018, and grants from the FDA Office of Generic Drugs and Division of Health Communication (2013-2016). No other disclosures are reported.

Funding/Support: This study was supported by an unrestricted grant from the Laura and John Arnold Foundation to Dr Kesselheim. Dr Kesselheim also receives support from the Harvard Program in Therapeutic Science and the Engelberg Foundation.

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES

1. Medicare Payment Advisory Commission. Databook: health care spending and the Medicare program. June 2018. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf. Accessed November 1, 2018.

2. US Centers for Medicare & Medicaid Services. 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf. Accessed November 1, 2018.

3. US Department of Health and Human Services. American patients first: the Trump administration blueprint to lower drug prices and reduce out-of-pocket costs. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf. Published May 2018. Accessed May 18, 2018.

4. US Department of Health and Human Services. Fixing healthcare: driving value through smart purchasing and policy. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/fixing-healthcare-driving-value-through-smart-purchasing-and-policy.html. Published May 2018. Accessed May 18, 2018.

5. US Department of Health and Human Services. HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Federal Register, 2018. 83 FR 22692. https://www.federalregister.gov/documents/2018/05/16/2018-10435/hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs. Accessed May 18, 2018.

6. US Centers for Medicare & Medicaid Services. CMS Drug Spending: Medicare Part B. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html. Published May 2018. Accessed May 18, 2018.

7. US Centers for Medicare & Medicaid Services. Medicare Prescription Drug Benefit Manual: Chapter 6: Part D Drugs and Formulary Requirements. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed May 18, 2018.

8. US Department of Health and Human Services. Secretary Azar: remarks on drug pricing blueprint. November 1, 2018. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html. Accessed May 18, 2018.

9. US Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed November 1, 2018.

10. US Centers for Medicare & Medicaid Services. 2018 ASP Drug Pricing Files: April 2018 Update. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2018ASPFiles.html. Published April 2018. Accessed November 1, 2018.

11. Dusetzina SB, Conti RM, Yu NL, Bach PB. Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending. *JAMA Intern Med*. 2017;177(8):1185-1188. doi:10.1001/jamainternmed.2017.1885

12. US Centers for Medicare & Medicaid Services. Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on

the Draft Guidance. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised-Guidance-052110.pdf. Published May 21, 2010. Accessed November 1, 2018.

13. Johnson NJ, Mills CM, Kridgen M. Millman; America's Health Insurance Plans. Milliman. Prescription Drug Rebates and Part D Drug Costs: Analysis of historical Medicare Part D drug prices and manufacturer rebates. Published July 16, 2018. https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf. Accessed November 1, 2018.

14. US Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2006Advance.html. Published February 18, 2005. Accessed November 1, 2018.

15. US Centers for Medicare & Medicaid Services. Medicare Part D: Direct and Indirect Remuneration (DIR). https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir. Published January 19, 2017. Accessed November 1, 2018.

16. SSR Health LLC. US Prescription Brand Net Pricing Data. https://www.ssrhealth.com/. Accessed November 1, 2018.

17. US Centers for Medicare & Medicaid Services. Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf. Published April 2017. Accessed November 1, 2018.

18. The Commonwealth Fund. Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status. https://www.commonwealthfund.org/publications/issue-briefs/2017/may/medicare-beneficiaries-high-out-pocket-costs-cost-burdens-income. Published May 12, 2017. Accessed November 1, 2018.

19. US Centers for Medicare & Medicaid Services. 2018 Resource and Cost-Sharing Limits for Low-Income Subsidy (LIS). https://www.medicaid.gov/state-resource-center/state-operations-and-technical-assistance/downloads/sota-update-20171213.pdf. Published November 2017. Accessed November 1, 2018.

20. America's Health Insurance Plans (AHIP). State of Medigap 2018. https://www.ahip.org/wp-content/uploads/2018/06/State_of_Medigap18_FINAL.pdf. Accessed November 1, 2018.

21. National Association of Insurance Commissioners. 2016 Medicare Supplement Insurance Experience Reports. https://www.naic.org/prod_serv_alpha_listing.htm#medsupp_loss. Published September 12, 2017. Accessed November 1, 2018.

22. US Centers for Medicare and Medicaid Services. Medicare Program; International Pricing Index Model for Medicare Part B Drugs. CMS-5528-ANPRM. https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs. Published October 30, 2018. Accessed November 1, 2018.

23. Office of Inspector General. High-price drugs are increasing federal payments for Medicare Part D catastrophic coverage. OIG, 2017. https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf. Accessed November 1, 2018.

24. Jung J, Feldman R. Growing reinsurance payments weaken competitive bidding in Medicare Part D. *Health Serv Res*. 2018;8(18):1-6. doi:10.1111/1475-6773.12866

25. Frakt A, Miller M. The case for restructuring the medicare prescription drug benefit [published online August 1, 2018]. *Health Serv Res*.

26. US Centers for Medicare & Medicaid Services. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf. Published August 7, 2018. Accessed November 1, 2018.

27. US Department of Health and Human Services. Trump Administration gives Medicare new tools to negotiate lower drug prices for patients. https://www.hhs.gov/about/news/2018/08/07/trump-administration-gives-medicare-new-tools-to-negotiate-lower-drug-prices-for-patients.html. Published August 7, 2018. Accessed November 1, 2018.

28. Roehrig C; Altarum. The impact of prescription drug rebates on health plans and consumers. Published April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf. Accessed November 1, 2018.

29. Congressional Budget Office. Proposals Affecting Medicare—CBO's Estimate of the President's Fiscal Year 2019 Budget. https://www.cbo.gov/publication/53906. Published June 5, 2018. Accessed November 1, 2018.

30. White House Office of Management and Budget. An American Budget—President's Budget FY 2019. https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf. Accessed November 1, 2018.

31. Hwang TJ, Kesselheim AS, Sarpatwari A. Value-based pricing and state reform of prescription drug costs. *JAMA*. 2017;318(7):609-610. doi:10.1001/jama.2017.8255

32. Medicare Payment Advisory Commission. June 2016 Report to the Congress: Medicine and the Health Care Delivery System. http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf. Published June 15, 2016. Accessed November 1, 2018.

Invited Commentary

Managing the Cost of Medicare Part B Drugs
Implications for the Program and Beneficiaries

Francis J. Crosson, MD; Jon B. Christianson, PhD

In this issue of *JAMA Internal Medicine*, Hwang et al[1] assess the costs to beneficiaries of implementing a draft proposal by the Department of Health and Human Services (HHS)[2] to reduce Medicare Part B costs. The plan would move certain expensive administered drugs from coverage under Medicare Part B to coverage under Medicare Part D. Medicare Part B covers drugs that are administered by infusion or injection in physician offices or hospital outpatient departments; Part D covers outpatient prescription drugs.

Author Audio Interview

Related articles pages 374 and 431

Based on Medicare claims data and information from the annual reports of the boards of trustees of the Medicare trust funds, the Medicare Payment Advisory Commission (MedPAC), on which we serve as Chairman (F.J.C.) and Vice-Chairman (J.B.C.), estimates that the Medicare program and its beneficiaries spent about $29.1 billion on Part B drugs in 2016, a cumulative increase of about 35% from 2013, and about $109.1 billion on Part D drugs in 2016, a cumulative increase of 26% from 2013.[3]

The intention is to reduce the cost of Part B drugs through the negotiation and utilization management processes of Part D plans. These processes are not currently allowed under Part B.